

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )  
FENFLURAMINE/DEXFENFLURAMINE) MDL NO. 1203  
PRODUCTS LIABILITY LITIGATION )  
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THIS DOCUMENT RELATES TO: )  
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SHEILA BROWN, et al. ) CIVIL ACTION NO. 99-20593  
 v. )  
 )  
AMERICAN HOME PRODUCTS )  
CORPORATION )

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8951

Bartle, J.

October 25, 2012

Doris F. Leggitt ("Ms. Leggitt" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.
2. William P. Leggitt, Ms. Leggitt's spouse, also has submitted a derivative claim for benefits.
3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In September, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Gregory R. Boxberger, M.D., F.A.C.C. Dr. Boxberger is no stranger to this litigation. According to the Trust, he has signed at least 74 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated June 24, 2002, Dr. Boxberger attested in Part II of Ms. Leggitt's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the

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3. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

range of 50% to 60%.<sup>4</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$407,738.<sup>5</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Kevin C. Sharkey, M.D., stated that claimant had "mild mitral insufficiency." Dr. Sharkey, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Sharkey also observed that claimant had "normal ventricular and atrial chamber sizes," with a left atrial dimension of 3.2 cm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii). Finally, Dr. Sharkey

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4. Dr. Boxberger also attested that claimant suffered from moderate aortic regurgitation. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension and a reduced ejection fraction are each one of the complicating factors needed to qualify for a Level II claim.

stated in one section of the report that claimant's ejection fraction was 55% and, in another section, noted that it was "approximately 50%." An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv).<sup>6</sup>

In February, 2004, the Trust forwarded the claim for review to Siu-Sun Yao, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Yao concluded that there was no reasonable medical basis for Dr. Boxberger's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Yao explained that claimant had an "RJA/LAA <20%." Dr. Yao also concluded that claimant had a normal left atrial dimension measuring 3.2 cm in the parasternal long-axis view and 3.9 cm in the apical four chamber view and that there was no reasonable medical basis for finding that claimant had an abnormal left atrial dimension. Finally, Dr. Yao concluded that there was no reasonable medical basis for finding a reduced ejection fraction and recorded that claimant's ejection fraction was 65%.

Based on Dr. Yao's findings, the Trust issued a post-audit determination denying Ms. Leggitt's claim. Pursuant

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6. Claimant also submitted an echocardiogram report prepared in August, 2002 by Dr. Boxberger based on her June 24, 2002 echocardiogram. In this report Dr. Boxberger stated that claimant had "moderate mitral regurgitation, based on RJA to LAA ratio of 21%." He also opined that Ms. Leggitt had a "mildly dilated left atrium at 4.1cm" and an ejection fraction of 55%.

to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup> In contest, claimant submitted affidavits from Dr. Boxberger, Roger W. Evans, M.D., F.A.C.P.,<sup>8</sup> F.A.C.C., G. Whitney Reader, M.D., F.A.C.P., F.A.C.C., and Dan A. Francisco, M.D., F.A.C.C. In his affidavit, Dr. Boxberger confirmed his previous findings that claimant had moderate mitral regurgitation with an RJA/LAA ratio of approximately 20%, a reduced ejection fraction measuring approximately 55%, and an abnormal left atrial dimension of 4.5 cm in the parasternal long-axis view. Dr. Evans agreed with the findings of the attesting physician and opined that claimant had "'moderate' mitral valve regurgitation with a RJA/LAA ratio of approximately 23%" and a reduced ejection fraction of 55% to 60%. Dr. Reader also stated that claimant had moderate mitral regurgitation and an ejection fraction "in the upper 50% range toward 60%."<sup>9</sup> In addition, Dr. Francisco attested that claimant had moderate mitral regurgitation with an RJA/LAA ratio of 30%, a

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Leggitt's claim.

8. Dr. Evans is also no stranger to this litigation. According to the Trust he has signed in excess of 318 Green Forms on behalf of claimants seeking Matrix Benefits.

9. Neither Dr. Evans nor Dr. Reader opined as to whether claimant had an abnormal left atrial dimension.

reduced ejection fraction measuring 60%, and that there was a reasonable medical basis for the attesting physician's determination that Ms. Leggitt had an abnormal left atrial dimension. Claimant argued, therefore, that there was a reasonable medical basis for her claim because four Board-Certified cardiologists independently agreed that she had moderate mitral regurgitation and a reduced ejection fraction, while two physicians also found that she had an abnormal left atrial dimension. Claimant further noted that the reviewing cardiologist, Dr. Sharkey, estimated claimant's ejection fraction to be 50%. Finally, claimant asserted that the auditing cardiologist "apparently did not understand the difference between his personal opinion ... and the 'reasonable medical basis' standard." (Emphasis in original.)

The Trust then issued a final post-audit determination, again denying Ms. Leggitt's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Leggitt's claim should be paid. On February 1, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4427 (Feb. 1, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting

documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 18, 2005, and claimant submitted a sur-reply on September 9, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>10</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Leggitt reiterates the arguments she made in contest; namely, that the opinions of Dr. Evans, Dr. Reader, and Dr. Francisco establish a reasonable medical basis for Dr. Boxberger's Green Form representations. In addition, claimant argues that the concept of inter-reader variability accounts for the differences between the opinions of claimant's physicians and those of the auditing cardiologist, Dr. Yao. More specifically, claimant asserts that there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable. Similarly, claimant asserts that there is also an "absolute" inter-reader variability of 18% when evaluating an ejection fraction using Simpson's Method, 16% when using wall motion index, and 19% when using subjective visual assessment. Thus, there would be a reasonable medical basis for the attesting physician's finding of an ejection fraction of 60% if the auditing cardiologist or the Technical Advisor measured the ejection fraction to be as high as 79%. Finally, claimant contends that the inter-reader variability for left atrial

dimension measurements is 0.81 cm. In his view there would be a reasonable medical basis for finding an abnormal left atrial dimension if the auditing cardiologist or the Technical Advisor measured the left atrium to be as low as 3.2 cm.

In response, the Trust argues that the opinions of Dr. Evans, Dr. Reader, and Dr. Francisco do not provide a reasonable medical basis for the claim because they "merely repeat[] the findings of Dr. Boxberger regarding moderate mitral regurgitation and an ejection fraction between 50% and 60%, without rebutting the findings of the Auditing Cardiologist." The Trust also notes that none of claimant's physicians addresses the findings of the reviewing cardiologist, Dr. Sharkey, who found only mild mitral regurgitation and a normal left atrial dimension. In addition, the Trust asserts that claimant's inter-reader variability argument cannot account for the auditing cardiologist's specific determination that there is no reasonable medical basis for Dr. Boxberger's findings of moderate mitral regurgitation, a reduced ejection fraction, and an abnormal left atrial dimension.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson found that:

In reviewing the transthoracic echocardiogram, there is a mild central mitral regurgitant jet seen on both the

parasternal and apical views. It is not holosystolic on spectral Doppler, which is consistent with mild mitral regurgitation. The mitral regurgitant jet was difficult to measure because the sonographer had a very narrow color box, which may not have included the entire jet. The left atrial area was also difficult to measure because the shallow depth in the apical views consistently excluded the superior wall. It was necessary to measure the left atrial area and the regurgitant jet area in two different views. Despite the difficulties with the measurements, I planimetered two mitral regurgitant jets/left atrial areas for measurements of  $2.6\text{cm}^2/16.2\text{cm}^2$  and  $2.9\text{cm}^2/16.9\text{cm}^2$  for ratios of 16% and 17%. Both of these ratios are less than 20%, which is consistent with mild mitral regurgitation.

Dr. Abramson also concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had an abnormal left atrial dimension. She "measured two left atrial diameters in the parasternal long axis of 3.6 cm and 3.5 cm. These are normal dimensions. I was unable to measure the left atrium in the apical views because the superior wall was not shown in the apical views." Dr. Abramson did, however, determine that there was a reasonable medical basis for finding a reduced ejection fraction in the range of 50% to 60%.

After reviewing the entire show cause record, we find claimant's arguments are without merit. First, claimant does not adequately contest the analysis provided by the auditing cardiologist and the Technical Advisor. She does not challenge Dr. Yao's conclusion that claimant's RJA/LAA was less than 20%.<sup>11</sup>

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11. For this reason as well, we reject claimant's argument that (continued...)

In addition, she does not refute Dr. Abramson's determination that claimant's RJA/LAA ratios were 16% and 17%, indicating mild mitral regurgitation.<sup>12</sup> Despite the opportunity to do so, claimant did not submit a response to the Technical Advisor's Report. See Audit Rule 34. Although claimant submitted the reports of several cardiologists, neither claimant nor her experts identified any particular error with the conclusions of the auditing cardiologist and the Technical Advisor regarding claimant's level of mitral regurgitation. They also did not explain the reviewing cardiologist's determination that only mild mitral regurgitation was present on her echocardiogram. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

We also are unpersuaded by claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Leggitt had moderate mitral regurgitation. The concept of inter-reader variability already is encompassed in the reasonable medical basis standard applicable to claims under the Settlement

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11. (...continued)  
the auditing cardiologist simply substituted his opinion for the diagnosis of the attesting physician.

12. Even if we found there was a reasonable medical basis for the Green Form representation of a reduced ejection fraction, the finding of a complicating factor alone, without the requisite level of mitral regurgitation, cannot establish a reasonable medical basis for Ms. Leggitt's claim.

Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor specifically concluded that claimant's echocardiogram demonstrated RJA/LAA ratios of 16% and 17%. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by  $\pm 15\%$  would allow a claimant to recover benefits with an RJA/LAA ratio as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.<sup>13</sup>

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for her claim. Therefore, we will affirm the Trust's denial of Ms. Leggitt's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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13. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in her statement that "[t]here is no reasonable medical basis for the Attesting Physician's claim that this [claimant] has moderate mitral regurgitation ... even taking into account inter-reader variability."